1859. Misbranding of Nembutal Capsules. U. S. v. Cottage Pharmacy and Peter P. Eacmen. Pleas of guilty. Each defendant fined $200. (F. D. C. No. 17798. Sample Nos. 11354–H, 11355–H.)

INFORMATION FILED: February 19, 1946, District of Massachusetts, against Cottage Pharmacy, a partnership, Boston, Mass., and Peter P. Eacmen, a member of the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of September 2 and December 7, 1944, from Chicago, Ill.

LABEL, WHEN SHIPPED: (Bottle) "100 Capsules Nembutal * * * (Pentobarbital Sodium, Abbott) Warning—May Be Habit Forming. Abbott 1½ grs. Caution—To be used only by or on the prescription of a physician or dentist."

NATURE OF CHARGE: That on or about February 15 and 21, 1945, the defendant removed the label described above from two bottles of the article, relabeled the bottles "Cottage Pharmacy Careful Prescriptionists * * * Use as directed," and disposed of the relabeled bottles of *Nembutal Capsules* to a certain individual.

The information charged further that the acts of the defendants resulted in the misbranding of the article in the following respects: Section 502 (d), the article contained a chemical derivative of barbituric acid, which derivative has been found to be and by regulations designated as habit forming, and the relabeled bottles of the article bore no label containing the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1) (2), the relabeled bottles bore no labeling containing directions for use, and they bore no labeling containing warnings against use of the drug in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration.

DISPOSITION: March 12, 1946. Pleas of guilty having been entered, the court imposed a fine of $200 upon each defendant.

1860. Misbranding of Konjola. U. S. v. The Arner Co., Inc., and Rolla Lawry. Pleas of nolo contendere. Fines, $250 against the corporate defendant and $750 against the individual defendant. (F. D. C. No. 14313. Sample No. 39545–F.)

INFORMATION FILED: May 14, 1945, Western District of New York, against the Arner Co., Inc., Buffalo, N. Y., and Rolla Lawry.

ALLEGED SHIPMENT: On or about January 17, 1944, from the State of New York into the State of California.

PRODUCT: Examination disclosed that the product consisted essentially of an aqueous solution of vegetable extractive, including emodin, together with pepsin, glycerin, compounds of iron, calcium, and manganese, salicylate or salicylic acid, and, possibly, caramel.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in circulars entitled "Here's A Simple Explanation of Why Millions Of Bottles of Konjola Have Been Bought By People From One End Of The Country To The Other," which circulars were shipped with the article, were false and misleading since the statements represented and suggested that the article would be effective as a tonic and digestive aid; that it would be effective other than as a laxative; that it would be effective in the treatment of indigestion, gas pains, bloating, digestive upset, intestinal sluggishness, run-down conditions caused by simple anemia, and rheumatism and neuritis pains caused by intestinal or digestive sluggishness; that it would help build rich blood; that it would be effective in relieving rheumatic and digestive pain and discomfort caused by accumulated wastes and poisons; that it would be effective to expel gas, deter gas formation, and reduce bloating; that it would be effective in treating weak stomachs; that it would sharpen the appetite; that it contained iron and pepsin in sufficient quantities to be effective as a tonic and digestive aid; and that it would be effective in treating simple anemia or rheumatic pains caused by intestinal sluggishness. The article would be effective only as a laxative, and it would not produce the effects represented and suggested.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the directions which appeared on the label provided for the continued administration of a laxative; and, Section 502 (f) (2), the labeling of the drug failed to bear a warning that it should not be used when abdominal pain was present, and its labeling also failed

to warn that continued use of the article might result in dependence on a laxative to move the bowels.

DISPOSITION: May 13, 1946. Pleas of nolo contendere having been entered, the court imposed a fine of $250 against the Arner Co., Inc., and a fine of $750 against Rolla Lawry.

1861. Adulteration and misbranding of Vivogen. U. S. v. 50 Cases of Vivogen. Default decree of condemnation and destruction. (F. D. C. No. 18357. Sample No. 27859–H.)

LIBEL FILED: November 16, 1945, Western District of Washington.

ALLEGED SHIPMENT: On or about August 23, 1945, by the Vivogen Co., from Los Angeles, Calif.

PRODUCT: 50 cases, each containing 4 1-gallon bottles, of *Vivogen* at Seattle, Wash.

The product contained approximately 0.24 milligram of iodine per gallon. It was stored at a warehouse at Seattle, to the account of an agent who solicited orders and filled them directly from the warehouse. At the office of the agent was a supply of circulars entitled "The Strange Case of Richard Near," in which representations were made for the use of the product in high blood pressure, kidney degeneration, cancer, Bright's disease, and heart trouble.

LABEL, IN PART: "Vivogen Artificially Mineralized Sea and Tap Waters * * * Active Ingredients * * * Potassium Iodide, .5232 Mgms. per U. S. Gallon (3.7854 Liters), of which actual Iodine is .4 Mgms."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, iodine 0.4 milligram per gallon.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of high blood pressure, kidney degeneration, cancer, Bright's disease, and heart trouble.

DISPOSITION: March 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1862. Adulteration and misbranding of posterior pituitary injection. U. S. v. 2 Boxes and 1 Box of Posterior Pituitary Injection. Default decree of condemnation and destruction. (F. D. C. No. 19258. Sample No. 8260–H.)

LIBEL FILED: On or about March 5, 1916, District of Connecticut.

ALLEGED SHIPMENT: On or about November 16, 1945, by E. R. Squibb and Sons, Biological Laboratories, from New Brunswick, N. J.

PRODUCT: 2 100-ampul boxes and 1 76-ampul box of *posterior pituitary injection* at Bridgeport, Conn. Examination showed that the potency of the product was substantially less than 10 U. S. P units of posterior pituitary per cubic centimeter and substantially less than the minimum potency specified by the United States Pharmacopoeia.

LABEL, IN PART: "Posterior Pituitary Injection Squibb U. S. P. XII 10 Units per cc."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Posterior Pituitary Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard.

Misbranding, Section 502 (a), the label statements, "10 International Units," "10 Units * * * 1 cc. size Equivalent to 10 U. S. P. XII," and "10 Units per cc. Each cubic centimeter is equivalent to 10 International Units," were false and misleading as applied to the article, the potency of which was substantially less than 10 units of posterior pituitary per cubic centimeter.

DISPOSITION: April 18, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

*See also Nos. 1852, 1853, 1861.